JOHNS HOPKINS MEDICINE JOHNS HOPKINS HEALTHCARE	Johns Hopkins HealthCare LLC **Pharmacy Public** **Pharmacy Management Drug Policies**	*Policy Number*	MEDS144
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This document applies to the following Participating Organizations:

Priority Partners

Keywords: Tavneos

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I. POLICY

A. Tavneos (avacopan) will require prior authorization for appropriate use. The process for initiating a prior authorization request can be found in policy PHARM 20.
   1. PPMCO members are subject to the Priority Partners formulary, available at www.ppmco.org.
   2. USFHP members are subject to prior authorization criteria, step-edits and days-supply limits outlined in the Tricare Policy Manual. Tricare Policy supersedes JHHC Medical/Pharmacy Policies. Tricare limits may be accessed at: http://pec.ha.osd.mil/formulary_search.php?submenuheader=1

II. POLICY CRITERIA

A. **Tavneos** may be approved for patients who meet the following:
   1. Patient is 18 years of age or older
   2. Documentation has been submitted showing all the following:
      a. Diagnosis of diagnosis of anti-neutrophil cytoplasmic autoantibody (ANCA)-associated vasculitis (granulomatosis with polyangiitis [GPA] or microscopic polyangiitis [MPA])
      b. Patients has active and severe disease evidenced by both of the following:
         I. New, persistent, or worsening clinical signs GPA or MPA
         II. Vasculitis is associated with organ-threatening manifestations (i.e., glomerulonephritis, central nervous system vasculitis, mononeuritis multiplex, , mesenteric ischemia, limb ischemia, etc.)
      c. A positive test for antibodies to either proteinase 3 (PR3) or myeloperoxidase (MPO)
      d. Tavneos will be used in combination with standard therapies (i.e. i.e., cyclophosphamide, azathioprine, mycophenolate mofetil, rituximab) and glucocorticoids
      e. Prescriber is, or has consulted with, a rheumatologist, nephrologist,or immunologist

III. AUTHORIZATION PERIOD/LIMITATIONS

A. Initial approval will be limited to 6 months of therapy
B. Continuation of therapy may be approved in 12-month intervals with documentation of one of the following:
   1. Patient has experienced disease remission while on Tavneos
   2. Patient has had clinical improvement defined by at least one of the following:
      a. Reduction in glucocorticoid dose

b. Reduction in relapse frequency
c. Improvement in eGFR

IV. EXCLUSIONS

A. Tavneos will not be approved for the following:
   1. Pediatric patients
   2. Patients with ANCA-associated vasculitis who are on dialysis
   3. Patients with severe hepatic impairment (Child-Pugh Class C)
   4. Any indications or uses that are not FDA-approved, or guideline-supported
B. The use of physician samples, or manufacturer product discounts, does not guarantee coverage under the provisions of the medical and/or pharmacy benefit. All pertinent criteria must be met in order to be eligible for benefit coverage.

V. REFERENCES

1. Tavneos [prescribing information]. Cincinnati, OH: Thermo Fisher Scientific; October 2021.
2. Jayne DRW, Merkel PA, Schall TJ, Bekker P; ADVOCATE Study Group. Avacopan for the Treatment of ANCA-Associated Vasculitis. N Engl J Med. 2021 Feb 18;384(7):599-609.

VI. APPROVALS

Signature on file at JHHC

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